



THE STATE
of **ALASKA**
GOVERNOR SEAN PARNELL

**Department of Environmental
Conservation**

DIVISION OF WATER
Directors Office

410 Willoughby Ave
Juneau, Alaska 99802
Main: 907.465.5135
Fax: 907.465.5274

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Water Docket No. EPA-HQ-OW-2014-0135
Environmental Protection Agency
Mail Code 2822T
1200 Pennsylvania Ave., NW
Washington, DC 20460

Attention: Docket ID No. EPA-HQ-OW-2014-0135

Dear Docket Manager:

The Alaska Department of Environmental Conservation (ADEC) has reviewed the U.S. Environmental Protection Agency's (EPA) proposed recommendations for *Updated National Recommended Water Quality Criteria for the Protection of Human Health* published in the *Federal Register* on May 13, 2014 (Federal Register, Vol. 79, No. 92, pp. 27303-27304). ADEC appreciates the opportunity to provide input on this important matter and offers the following general and specific comments on this proposal.

The Clean Water Act (CWA) clearly directs primacy for the establishment of water quality standards (WQS) and the periodic review of those standards to the states. The CWA does give EPA authority to approve or disapprove the *standards* the states develop, but it does not give EPA the authority to approve or disapprove of the *process* states use to review and implement those standards. EPA must recognize that states have different climatic and geophysical factors to consider when establishing WQS, as well as varying legal and policy considerations.

While ADEC appreciates EPA's work on these draft criteria recommendations, we must point out that EPA does not have a legal obligation to issue these revisions. EPA does, however, have a legal obligation under the CWA to take action on state WQS revisions within 90 days of receipt. In many cases, states wait years for EPA action on state WQS revisions. We recommend that EPA propose changes that would allow for automatic EPA approval of state WQS revisions that are more stringent than the state's previous standards. EPA should consider language to the effect of "any standard that is more stringent than a previous standard is assumed to meet the requirements of the Act if no action is taken by the Administrator within 90 days." This would be consistent with the Alaska Rule in 65 FR 24644, because while the CWA § 303(c)(3) requires EPA to 'approve' a standard, 'approving by silence' can still constitute an 'approval.' This would free up the resources necessary to review previously submitted state regulations updates in a timely manner.

On June 30, 2014, during an Association of Clean Water Administrators (ACWA) teleconference between state and EPA staff, EPA staff made the statement that early internal discussions are taking place at the national level regarding potential revisions to the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (2000) and that such an effort may continue over the next two years. ADEC strongly recommends this course of action and that EPA commits the necessary resources to revisit the methodology behind the development of Human Health Criteria (HHC). ADEC believes the efforts to inform and educate the public on adoption of the 2014 criteria will be fundamentally flawed if EPA determines that the existing methodology is not appropriate to establish the risk levels associated with the consumption of surface water and/or aquatic life.

ADEC believes that adoption of the 2014 criteria will not create the regulatory environment states or stakeholders consider practical or even feasible in many cases. It is neither efficient nor transparent of EPA to require WQS that may be using out-of-date methods or a process that may not be protective of human health. Should EPA determine that a revisit and revision to the 2000 methodology will take place, ADEC requests EPA's formal engagement with states in every step of the process. This should include participation in both science and policy working groups, early consideration of implementation tools, and the availability of designated funding for state efforts to address data gaps associated with the study of fish consumption rates by certain at-risk populations.

If EPA chooses not to rescind the 2014 recommended criteria, ADEC is providing the following comments for consideration. Rather than address the entire suite of scientific issues associated with each of the 94 proposed criteria including establishment of reference dosage, cancer slope factors, reliability of studies used, ADEC is providing some general comments on EPA's effort to update the proposed criteria and specific aspects of the HHC methodology.

1. Compounded Conservatism in the Human Health Criteria formula

The formula used to derive the HHC in the EPA methodology¹ considers risk, toxicity, and exposure values. While developed more than 20 years ago, many of the values and assumptions remain in effect and have substantive impacts on the proposed criteria. The term "conservatism," in the context of HHC, describes the use of assumptions and defaults that are likely to overstate the true risks from exposure to substances in toxic concentrations. ADEC takes issue with EPA's overly conservative approach and subsequent adoption of certain values and assumptions.

The policy choices used in EPA's approach to deal with uncertainty and variability provides a fundamental challenge to states as many recommended values are orders-of-magnitude higher than needed to afford the degree of protection targeted by most states and EPA.²

The National Council for Air and Stream Improvement Report (2012) on the 2000 methodology notes:

¹ United States Environmental Protection Agency (EPA). 2000a. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. EPA/822/B-00/004. Washington, DC: United States Environmental Protection Agency Office of Science and Technology.

² NCASI (2012) A Review of Methods for Deriving Human Health-Based Water Quality Criteria with Consideration of Protectiveness. Arcadis

EPA's Risk Assessment Task Force has suggested that 'when several parameters are assessed, upper-end values and/or central tendency values are generally combined to generate a risk estimate that falls within the higher end of the population risk range' and 'an exposure estimate that lies between the 90th percentile and the maximum exposure in the exposed population [should] be constructed by using maximum or near maximum values for one or more of the most sensitive variables, leaving others at their mean values,' (EPA 2004)³.

The HHC formula considers numerous factors to derive HHC values including substance toxicity, body weight, drinking water intake, fish/shellfish consumption, and exposure to other sources (i.e. relative source contribution). It also considers implicit sources such as cooking loss, duration of exposure, exposure concentration, bioavailability, and bioaccumulation/trophic level of fish. In most of these cases the value chosen was derived from the upper-end or maximum value possible.

- The reference dose and cancer slope factors typically include **multiple safety factors** of 3 to 10 times for each type of uncertainty that lower the final value by several orders of magnitude, (e.g. 3000).
- The proposed national fish intake value is based on the **90th percentile** of the adult population. Further, EPA recommends that states with high-consuming subpopulations use the 90th percentile of those populations, which is essentially the 90th percentile of the 90th percentile of the general population of the state.
- The drinking water intake is based on the **90th percentile** for adults.
- The body weight is the only factor in the HHC formula that uses the **mean** value for adults.
- The relative source contribution further multiplies the final HHC by another **factor of 0.2**.

The effect of these choices is a regulatory value that is neither reflective of the actual risk most waters pose to human health or a value that can even be measurable in many cases; therefore, negating the actual utility of the criteria.

The EPA methodology acknowledges that conservative assumptions in the calculation of reference dose values (RfDs) and total exposures slightly exceeding the RfD are unlikely to produce adverse effects in humans.⁴ A 2004 study conducted by a California Office of Environmental Health Hazard Assessment⁵ concluded that the values of 22 of the 57 chemicals studied were “unreasonably conservative” and that risk was better represented when professional judgment was applied. Overly protective criteria may result in poor prioritization that divert resources away from activities posing actual environmental impacts and instead focus treatment, restoration and permitting resources on achieving criteria levels for which risk has been over-estimated.

Examples of overly conservative criteria

The following are two examples of exactly how “unreasonably conservative” some of the new criteria are.

³ United States Environmental Protection Agency (EPA). 2004. *An examination of EPA risk assessment principles and practices*. EPA/100/B-04/001. Washington, DC: United States Environmental protection Agency Office of the Science Advisor.

⁴ United States Environmental Protection Agency (EPA). 2000a. *Methodology for deriving ambient water quality criteria for the protection of human health (2000)*. EPA/822/B-00/004. Washington, DC: United States Environmental Protection Agency Office of Science and Technology. pg. 4-4

⁵ Howd, R.A., Brown, J.P., Fan, A.M. 2004. Risk assessment for chemicals in drinking water: estimation of relative source contribution. *The Toxicologist* 78(1-S).

a. Cyanide

EPA has concluded that the previously RfD of 2×10^{-2} mg/kg*day should be updated to 6×10^{-4} mg/kg*day. The principle study by the National Toxicology Program (NTP, 1993) used to calculate the reference dose for cyanide was based on decreased weight in male rats orally exposed to cyanide. The study had a lower-bound confidence limit on the benchmark dose of 1.9 mg/kg*day. An uncertainty factor of 3000× was applied to account for interspecies extrapolation (10×), intraspecies variation (10×), subchronic to chronic extrapolation (10×), and deficiencies in the database (3×) (USEPA, 2010). The result of this revision is that the water-and-organism criterion decreased from 140 µg/L to 3 µg/L.

The results of the NTP 1993 study should be considered to be informative but the results also concluded that: “In summary, administration of low concentrations of sodium cyanide in drinking water to rats and mice for 13 weeks resulted in no clinically significant body weight, organ weight, histopathologic, or clinical pathology changes; and that “sub-chronic exposure to low concentrations of cyanide in drinking water does not present a significant human health hazard (NTP, 1993).”

ADEC does not question the fact that cyanide is a toxic compound and has long been known to be detrimental to human health but having a criterion based on the results of this study, compounded with a 3000-fold margin of safety seems excessive. Furthermore, most of the exposure issues documented in different studies were associated with respiratory or dietary pathways rather than through drinking water. A drinking water standard of 200 µg/L has already been established by EPA as the maximum contaminate level under the Safe Drinking Water Act and should serve as the recommended human health criterion for consumption of aquatic organisms and water.

b. Anthracene

The updated 2014 human health ambient water quality criteria for anthracene are about two to three orders of magnitude lower than the previously recommended criteria i.e., the water-and-organism criterion decreased from 8,300 µg/L to 200 µg/L, and the organism-only criterion decreased from 40,000 µg/L to 200 µg/L. Anthracene values were derived in a manner similar to that of cyanide by using an uncertainty factor of 3000, but in the case of anthracene the bioaccumulation value acts as the definitive driver of the lower criterion as both the water-and-organism and organism-only values are set at 200 µg/L. Previous HHC applied a laboratory-derived bioconcentration value of 30 L/kg. The new methodology uses modeled values where there is minimal evidence that supports true bioaccumulation will be close to that of the proposed values. Such a practice is problematic, especially when the exposure pathways for anthracene are very limited in most state waters.

Recommendations:

Rather than continuing to utilize the overly conservative interpretation of the EPA methodology, ADEC encourages EPA to heed its own recommendations noted in the EPA 2004 task force report and develop additional guidance using one of the following approaches:

Option 1: Set overall risk levels in nationally recommended HHC using the most sensitive factor for a pollutant such as the drinking water intake or fish consumption rates; use the mean for other factors (e.g. relative source contribution, body weight, bioaccumulation factors) in the HHC formula; and allow states to adapt the HHC formula to consider actual exposure, duration, and

concentration rates. Also, EPA should limit the use of compounded safety factors by not using results from single studies of nonhuman species to set RfD and cancer slope factor. Arbitrary use of the highest or most restrictive values for each of the inputs of the HHC formula, including that of fish consumption rates, does not demonstrate sound risk management policy, but rather complete risk avoidance. This is an approach more attuned to defending against environmental litigation than supporting environmental science.

Option 2: EPA should develop or allow states to use probabilistic modeling methods in determining HHC regulatory values. Establishment of *ranges* of values rather than specific endpoints of concern provides states with the flexibility needed to consider the actual degree of risk present to the most “at risk” populations rather than simple adoption of national assumptions.

Option 3: EPA should automatically approve state adoption of nationally recommended criteria even where higher fish consumption rates may occur. Populations with higher fish consumption rates would be considered protected by the conservatism of other factors in the HHC formula.

EPA has a responsibility to issue national criteria recommendations to states for the protection of particular designated and existing uses while states are provided with the responsibility of implementing criteria. The EPA methodology is clear in its intent to provide states with flexibility in adjusting levels in accordance to local or regional data. However, the guidance does not include specific guidelines regarding type, amount, and quality of additional data required to adjust criteria. This leaves states with little recourse other than to either delay adoption or engage in lengthy, resource-intensive processes. If EPA is to issue *nationally* (emphasis added) recommended criteria, including subsistence-based values, then states should be able to assume that said levels will be protective of their populations rather than having to contemplate whether EPA will approve of the criteria a state chooses to adopt.

2. General Comments on the EPA Fish Consumption Rate (FCR) methodology

The External Peer Review report on FCR⁶ identifies several issues that EPA should consider before finalizing the proposed criteria. The report notes that some of the assumptions used in the EPA methodology may be suspect including how dietary data (types of fish and exact amounts of fish) taken from the National Health and Nutritional Examination Survey (NHANES) were handled. This is important information for those states weighing whether or not to include the consumption of anadromous fish as part of state-specific FCR.

The report also refers to differences in the accepted methods used by the National Cancer Institute (NCI) and those considered by EPA in the proposed criteria and subsequent methodology:

“The document demonstrated a sound understanding of the NCI method. However, there are serious concerns about the validity of the estimates produced by the modified EPA method. In particular, this method makes a number of approximations, nor does it fully justify the approximations that are made.” (p.4)

“I am concerned that the statistical methods utilized to estimate the distribution of usual fish intake is not well justified, and could lead to biased estimates.” (p.5)

⁶ External Peer Review of EPA’s Draft Document *Fish Consumption Rates* (2014). Publication No: 820-R-14-003

The NCI method is anecdotally referred to by many EPA Region 10 stakeholders as being the “gold standard” or the more appropriate way of estimating usual dietary intake and accompanying statistical analyses. While the EPA *Final Estimated Fish Consumption Rates*⁷ (Final Report) notes that the EPA method was developed to simplify many of the computations and statistical complexity, it is extremely important to states to know the extent that distributions may change and specific instances when one method is used versus another, and the accuracy of the chosen method.

The EPA Final Report notes that “some percentiles may be more biased than others” but does not elaborate on how these assumptions may affect specific percentiles. This is an issue ADEC would like to see addressed prior to finalizing the proposed criteria if EPA is to expect states to provide protection to the most “at risk” populations. One question that arises is what comprises the upper 90th percentile and how biased might these values be if one method is chosen over another.

Another issue with the NHANES FCR data is that the reported fish meals were obtained from numerous sources and included fresh, frozen, prepared and canned fish products that may have been produced in other regions of the United States or other countries and, consequently, not derived from local state waters. Thus, while the reported FCR may be correct if these are considered to be an accurate accounting of sources, the degree of risk posed from the consumption of fish may vary considerably as concentration of contaminants in fish may not relate to contaminant concentrations in the different waters.

The report notes that the design of the NHANES survey may not provide an accurate representation of Asian and Pacific Islander’s or Native American/Alaskan Natives. These two groups compose a significant part of the population in the Northwest and over 20% of Alaska’s total population.⁸ If biases are present in the NHANES data because these subsets of the population may not have been adequately represented, ADEC is concerned that bias may create inaccurate FCR values.

Recommendation

- EPA should develop additional guidance on application of the EPA-modified method and how states should or should not use this model.
- EPA should provide additional accounting of how biases affect particular demographics and how they affect the final national FCR.

3. Relative Source Contribution (RSC)

The EPA 2014 criteria recommend a default RSC value of 20 percent, which essentially requires states to lower the allowed exposure by 80 percent for ambient water quality criteria. ADEC questions whether enough national data is available on the influence of other sources, against that of specific surface waters, exists to justify such a small percentage being attributed to the ingestion of surface water and aquatic life. Until a time when EPA can effectively characterize the amount and degree of exposure risk posed from specific sources of pollutants, the default RSC should be limited to 1 (100 percent of RfD value) rather than acting as the default “catch-all” when additional data is not available. This will ensure that any regulatory action taken on the part of water quality will have a measureable public health benefit.

⁷ EPA. (2014) Final Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010). EPA-820-R-14-002

⁸ 2013 State Census. Downloaded from <http://quickfacts.census.gov/qfd/states/02000.html> on June 10, 2014

a. Scope of the Clean Water Act (CWA)

ADEC believes that the development of HHC values that attempt to account for sources outside of the scope of the CWA is not appropriate and should be left to those regulatory mechanisms that best account for exposure from those specific pathways. ADEC firmly believes that the purpose of the CWA is to address potential exposure from contaminants to *primary sources* (National Pollutant Discharge Elimination System (NPDES) permitted activities) and other CWA-regulated activities and should not serve as the means of regulating or accounting for **all** sources of risk.

ADEC appreciates the desire to apply the precautionary principle in cases where research has yet to accurately define the actual RSC for each regulated chemical. However, application of the blanket 20 percent value is more appropriate for screening criteria rather than imposing regulatory limits. The use of overly conservative RSC, without a substantial amount of scientific data, demonstrates that policy choices, rather than sound science, are driving the decision making process and undermine the integrity of EPA and state regulatory efforts. Defining the presence and amount of concern the public should have about exposure to a particular pollutant is best regulated by those programs that are most familiar with the paths of greatest concern (e.g., Federal Food and Drug Administration, or State Air Quality programs for fugitive dust concerns).

The need to refocus attention solely on actions attributed to CWA-associated actions is further illustrated by the fact that EPA has yet to develop specific policy guidelines for establishing inhalation and dermal exposures – two significant factors that are included in the list of RSC factors for consideration. A water quality standard can only affect (i.e., reduce) risk from exposure to those sources that are directly associated with state surface waters. Efforts to account for exposure to the myriad of toxins potentially present in the environment should take place through regulations that target those sources if meaningful toxin reduction is to occur. EPA presumes that other toxin sources are present in concentrations that may pose a risk to human health but makes that assumption without empirical data for each pollutant. The degree of risk can easily be overestimated and place an unnecessary burden on states and on entities to which overly restrictive criteria will apply.

b. Efforts to link different EPA programs may result in unanticipated consequences

Another example of how a default RSC value is inappropriate for HHC, is the application of the 20 percent default in both the Safe Drinking Water Act (SDWA) and the CWA.

“Another reason for the 2000 Human Health Methodology is the need to bridge the gap between the differences in the risk assessment and risk management approaches used by EPA’s Office of Water for the derivation of [ambient water quality criteria] (AWQC) under the authority of the CWA and Maximum Contaminant Level Goals (MCLGs) under the Safe Drinking Water Act (SDWA). Three notable differences are the treatment of chemicals designated as Group C, possible human carcinogens under the 1996 proposed cancer guidelines, the consideration of non-water sources of exposure when setting an AWQC or MCLG for a noncarcinogen, and cancer risk ranges.”⁹

The fundamental challenge to consider when trying to align MCLGs and AWQC is that MCLGs are goals while HHC are regulatory limits and efforts to merge the two concepts offer mixed results. MCLGs provide the foundation for Maximum Contaminant Limits (MCLs); the actual regulatory limits for application in drinking water programs. MCLGs act as the starting point, are set at levels below that where there is not a known risk, and contain a set margin of error. MCLs are then set at

⁹ EPA Methodology 2000. Page 1-5.

levels that are both reflective of the science behind the MCLG *as well as* accounting for the technical and economic factors associated with the removal of said contaminants. Such a comprehensive approach demonstrates how technical and practical considerations act to establish sound regulatory actions.

In the HHC formula, the drinking water intake pathway is a driving risk factor. Currently, there are pollutants that have proposed rates not equal to the MCL for the same pollutant under the SDWA (i.e. cyanide, toluene, 1,2,4-trichlorobenzene). EPA states that there are no current plans to update the MCL. Maintaining different values to regulate risk from drinking water intake causes an inconsistency between EPA programs and is a point requiring additional clarification. Essentially, if drinking water is in fact a risk, it should be reflected in the initial RSD as well as RSC specific values.

c. Burden of Proof

While EPA does provide some guidance and allow the RSC value to be replaced (adjusted upward) when sufficient data is present, the provision of such data places an enormous burden on states if they are to account for the wide variety of pollutant exposures potentially present in a community. In fact, the regulation places much greater emphasis on noting whether something is NOT present rather than actually presenting a known and accountable risk to the general public. EPA openly recognizes the complicated nature of conducting such risk assessment work in the 2000 methodology and its limits.

Determining how various subgroups fall within the distributions of overall exposure and how the combination of exposure variables defines what population is being protected is a complicated and, perhaps, unmanageable task, depending on the amount of information available on each exposure factor included. (EPA, 2000. HHC Methodology. Section 4.2.4)

Marine life are currently considered to be part of the 80 percent of “additional” sources to consider (although certain species are also considered as estuarine) This decision by EPA is incredibly challenging for a number of reasons, the least of which is that the majority of fish eaten in Alaska, much less the U.S., come from marine sources. If Alaska includes marine life (including anadromous species) as part of its fish consumption rate, it goes to reason that the RSC should be adjusted upwards as this “potential source” will be accounted for. ADEC would like EPA to establish an official position on protocols for including marine species and how the RSC can be adjusted without requiring states to collect inordinate amounts of data to support such conclusion(s).

Recommendations

- RSC should be limited to only those factors that are actually addressed through the CWA.
- EPA should reconsider how the SDWA and CWA interact with one another and formally consider consistency in regulatory levels.
- EPA should establish an official position on protocols for the inclusion of marine species.
- EPA should allow states to adjust the RSC without requiring states to collect inordinate amounts of data to support such conclusion(s).

4. Consideration of Trophic Level and Bioaccumulation Factors

The use of the trophic level weighting when calculating bioaccumulation factor values recommended by the Scientific Advisory Board (SAB)¹⁰ were meant to be used for “screening level decision

¹⁰ Science Advisory Board (SAB) Review of the Estimation Programs Interface Suite (EPI Suite™) (2007).

making” not necessarily regulatory limits. These levels may not reflect regional geochemical/biological differences, including metabolic adaptation. The greatest risk to human health from consumption of fish is generally understood to result from the presence of persistent, bioaccumulative, and toxic (PBT) chemicals, rather than through incidental exposure to a particular pollutant. Assumptions regarding the presence or absence of a pollutant does not serve the public interest.

Recommendations

- Rather than assigning a particular bioconcentration value based on the presumption that a pollutant is present, states should be allowed the flexibility to consider this factor during the assignment of site-specific criteria when confirmation testing may indicate the presence of a particular pollutant via ambient water quality studies.
- EPA should place additional emphasis and resources in its assessment and monitoring program to help states accomplish this task. This pro-active approach would help states determine that regional or site-specific criteria values reflect the actual degree of exposure risk to a particular pollutant posed from fish consumption.
- EPA should allow states to establish a range of bioaccumulation rates based on the persistence of a pollutant in aquatic species actually present in a state rather than use a general deterministic approach. Such an approach could include assignment of an additional weighting factor(s) specific to the potential of risk being present. This process would best be applied using:
 - a parameter-by-parameter basis,
 - state dietary patterns data, and
 - specific aquatic species present in that region and considered to be a species of consumption.

ADEC generally supports using a bioaccumulation factor (BAF) for the proposed criteria as the BAF is a more comprehensive approach when considering all of the different risk factors that lead to concentrations of toxins in fish tissue. ADEC takes issue with the use of fixed trophic level assignments and BAFs as determined by the Estimated Program Interface (EPI) Suite model to determine regulatory limits and suggests further consideration of how BAFs and trophic position are established and applied in the HHC formula. The EPI-Suite clearly states that the model was developed for temperate waters and not recommended for arctic, sub-tropical, or tropical conditions. Furthermore, the model was calibrated using several species that are not present in Alaska, thus providing overly conservative values for Alaska’s waters.

Recommendation

EPA should provide guidance on how the EPI-Suite model can be calibrated to accommodate the natural conditions (i.e., temperature, fish weight, lipid content), as well as allow for the HHC formula to consider the complete absence of a pollutant when establishing site-specific criteria.

In conclusion, ADEC believes that it is essential for states to have reliable data, as well as the flexibility necessary to make best judgment decisions on how to apply such information in their water quality standards. While the proposed 2014 HHC demonstrate a step forward for science, there are numerous places where additional research should be considered before the criteria are finalized. States should have additional opportunity to comment on many of the assumptions used in the HHC methodology including uncertainty values, the role of RSC values and how they can be

adjusted to reflect actual exposure rates, and application of EPI-Suite model for bioaccumulation when species or location specific data is not available.

ADEC appreciates the opportunity to comment on the proposed rule and appreciates the work EPA has done to date. If you have any questions regarding ADEC's comments, please feel free to contact Nancy Sonafrank at (907) 451-2726 or nancy.sonafrank@alaska.gov.

Sincerely,

A handwritten signature in cursive script that reads "Michelle Hale".

Michelle Hale
Director

Cc Dan Opalski, EPA Region 10
Angela Chung, EPA Region 10

Water Docket Manager

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August 12, 2014

Bcc Nancy Sonafrank, DEC/Fairbanks